

Arrow International  
c/o Teleflex Medical  
IDA Business & Technology Park  
Dublin Road, Athlone  
Co. Westmeath, Ireland

12<sup>th</sup> April 2018

## **URGENT - FIELD SAFETY NOTICE**

<b>Commercial Name of Affected Product:</b>	<b>Various Arrow Products Refer to Appendix 2 for full product details</b>
<b>Type of action:</b>	<b>Recall</b>
<b>Arrow Reference:</b>	<b>EIF-000256</b>
<b>Product Codes/Lot Numbers</b>	<b>Refer to Appendix 2</b>

Dear Customer,

### **Details of affected devices**

Arrow International is issuing a recall for the above listed product.

### **Description of the problem**

Arrow International is recalling the product referenced in Appendix 2 because the packaging may not be sealed. If the packaging is compromised in this manner, the sterility of the product cannot be guaranteed. If a non-sterile product is used, there is potential for infection to occur. No patient injuries have been reported related to this issue.

Our records indicate your facility has received product in scope of this field safety notice.

### **FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS**

#### **ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF**

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in Appendix 2, then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.
3. If you have stock from the affected product as referred to in Appendix 2, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned below who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

**INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT**

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
2. As a Distributor you are required to confirm to Arrow International that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Arrow International.
4. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Arrow International.

Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Arrow International distribute directly will be notified by Arrow.

**Arrow International**

Arrow informs all customers, employees of Arrow and distributors on this Field Action.

**Transmission of this Field Safety Notice**

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organisation.

**Contact reference person**

Should you require any further information or support concerning this issue, please contact:

**Customer Service**

**Contact:** Shane Kenny

**FAX:** +353(0)1 4370773

**Telephone:** +353 (0)90 6460869

**E-mail:** Recalls.intl@teleflex.com

Arrow International is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

***For and on behalf of Arrow International,***



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***Padraig Hegarty VP, QA***